### REMARKS

The foregoing amendments and these remarks are in response to the Final Office Action dated June 18, 2008. This amendment is accompanied by a Request for Continued Examination. Applicant also respectfully requests a request for a one-month extension of time and authorization to charge Deposit Account No. 50-0951 for the appropriate fees.

At the time of the Office Action, claims 1-10 were pending in the application. Claim 10 has been withdrawn from consideration. Claims 1-8 were rejected under 35 U.S.C. §112, second paragraph. Claims 1-9 were rejected under 35 U.S.C. §103(a). The rejections are discussed in more detail below.

#### I. Claim Rejections under 35 U.S.C. §112

Claims 1-8 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action stated that the recitation of "comminuted solid polyisoprene" and "organic solvent" were vague and indefinite.

In order to overcome this rejection, claim 1 has been amended as follows:

- the expression "comminuted solid polyisoprene" has been changed to "a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range" (support is found in the description at least on page 3, lines 11-22); and
- the expression "organic solvent" has been changed to "an aliphatic hydrocarbon with 12-22 carbon atoms" (support is found at least in original claim 5 and in the description on page 4, lines 15-17). As a result, original claim 5 has been cancelled and the expression "organic solvent" has also been changed to "an aliphatic hydrocarbon with 12-22 carbon atoms" in claims 6 and 7.

Based on these amendments, withdrawal of the rejection is thus respectfully requested.

## II. Rejections on Art

Claims 1-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,471,983 to Veeger et al. (hereafter "Veeger") as evidenced by Kraton IR 401 brochure of record in view of U.S. Patent Publication No. 2003/0044469 to Viladot ("Viladot").

It is first to be noted that water is present in the skin composition of *Veeger* since the polyisoprene used was in the form of latex, in particular the Kraton IR 401 latex, i.e., a water-based emulsion of an anionically polymerized polyisoprene with a high cis 1,4 content. On the contrary, the polyisoprene employed in the cosmetic composition of the present claims is an anhydrous polyisoprene.

In particular, the polyisoprene used in the claimed composition is obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range.

A specific example of the polyisoprene used in the composition recited in the present claims is that obtained by the process comprising the steps of a) comminuting the solid polyisoprene Kraton a 310 with a molecular weight of about 3,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight of 100,000 (see Examples of the present application and the description on page 3, lines 9-22).

Therefore, in order to better distinguish the presently claimed cosmetic composition from that of *Veeger*, in amended claim 1 the term "comprising" has been changed to "consisting of".

In this manner, the ingredients of the cosmetic composition of the present claims have been limited to those listed in amended claim 1 and the presence of water has been excluded.

In order to further overcome the rejection based upon a combination of *Veeger* with *Viladot*, a Declaration duly signed by the inventor of this application is enclosed, in which the inventor shows by experimental data that the combinative effect of the presence of the three components, i.e. the polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, the oleophylic modified smectite clay and an aliphatic hydrocarbon with 12-22

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carbon atoms, is essential in order to achieve a <u>stable</u> cosmetic composition having <u>high film-forming property</u>, which provides for the deposition of a <u>homogeneous</u> long lasting film on the facial skin, lips and eyelashes.

Indeed, as shown in point 4 of said Declaration, a comparable product without the olcophylic modified smectite clay (i.e. REM 513.33), a comparable product in which the polyisoprene of the present application has been substituted by a polyisoprene latex (i.e. REM 513.34), and a comparable product in which the polyisoprene of the present application has been substituted by a polyisoprene with a very low molecular weight (i.e. REM 51335) are all unstable and with unhomogeneous aspect and therefore unsuitable for the preparation of a cosmetic composition suitable for application to facial skin, lips and eyelashes.

In the attached Declaration, the inventor has extensively proved and explained the effect of the components present in the cosmetic composition of the present invention, when considering the cited prior art. From the Declaration, it can be seen that it is evident that the combined effect of the presence of the three claimed components, namely a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range; an oleophylic modified smectite clay; and an aliphatic hydrocarbon with 12-22 carbon atoms are all essential to achieve a stable cosmetic composition with a high film-forming property suitable for application to facial skin, lips and eyelashes. Only a product compared according to the present claims exhibited a homogeneous creamy fluid aspect, a good film-forming property and a short drying time after application, and was thus the only product suitable for application to facial skin, lips and eyelashes as required by the present claims.

It is clear from the experiments carried out by the inventor, and attested to in the attached Declaration, that neither *Veeger* nor *Viladot*, either individually or combined, teach or suggest the claimed composition. Claim 1 is thus believed to relate to patentable subject matter, and to be in condition for allowance. The dependent claims are also believed allowable because of their dependence upon an allowable base claim, and because of the further features recited.

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# III. Conclusion

Applicants have made every effort to present claims which distinguish over the prior art, and it is thus believed that all claims are in condition for allowance. Nevertheless, Applicants invite the Examiner to call the undersigned if it is believed that a telephonic interview would expedite the prosecution of the application to an allowance. In view of the foregoing remarks, Applicants respectfully request reconsideration and prompt allowance of the pending claims.

Date: 10/17/09

Respectfully submitted,

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of Giuseppe Maio

Serial No. 10/792,100 Group Art Unit: 1616

Filed: March 3, 2004 Examiner: Landau, Sharmila Gollamudi

For: COSMETIC COMPOSITION CONTAINING POLYISOPRENE

## DECLARATION UNDER 37 CFR § 1.132

Honorable Commissioner of Patent and Trademarks Washington, D.C. 20231

Sir:

- I, Giuseppe Maio, a citizen of Italy, hereby declare and state:
- 1. I attended a Technical School (I.T.I.S.) in Salerno (Italy) with specialisation in Chemistry, where I obtained a diploma in 1965. From 1966 to 1967 I had a job in the food analysis department of Cirio S.p.A. in Naples and from 1997 to 1986 I worked in the cosmetic field in some cosmetic companies in Milan, particularly as R&D Manager for Cosmetic Make-up in International Chemical Cosmetic & Company S.p.A. in Milan from 1980 to 1986. Since 1986 to date I have been Exploratory Research Manager in the Assignee company Intercos S.p.A. I am inventor and applicant in several US patents such as US 6,372,232, US 6,660,253, US 6,953,543.

- 2. I am the inventor of the above referenced patent application and I am familiar with the references applied in the Office Action mailed June 25, 2008.
- 3. Cosmetic products for make-up of face, lips, eyelashes etc often suffer from the drawback that, when they come into contact with e.g. the fingers or clothing, they tend to smudge or solid these surface. In addition, in some cases the make-up can also appear to be not homogeneous.

Therefore, in order to avoid these problems cosmetic products suitable for application to facial skin, lips and eyelashes have to be endowed with the following properties: be stable, have high film-forming property and provide for the deposition of a homogeneous, long lasting film onto the facial skin, the lips and the eyelashes.

4. I made a lot of experiments in order to select the specific components for a cosmetic composition capable of being endowed with the all the above required properties.

During my experiments, I have surprising found that the combination of 1) a polyisoprene (from 2 to 25% (w/w)) obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) an oleophylic modified smectite clay (0.05 to 20% (w/w)) and 3) an aliphatic hydrocarbon with 12-22 carbon atoms (from 1.1 to 90% (w/w)), the balance comprising conventional cosmetic excipients, is critical in order to achieve a cosmetic composition which is stable and provides for the deposition of a homogeneous, long lasting film onto the facial skin, the lips and the eyelashes.

In order to obtain the above desired composition, I have performed the following assays which results are depicted below.

In my experiments I have compared the properties of the following products:

- "REM 513.32" is an <u>invention product</u> with the following composition: a polyisoprene (10.0 w/w) obtained by the process comprising the steps of a) comminuting the solid polyisoprene Kraton IR 310 with a molecular weight of about 3,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight of about 100,000; as oleophylic smectite clay, disteardimonium hectorite (6.0 w/w); as an aliphatic hydrocarbon with 12-22 carbon atoms, isododecane (79.0 w/w); and colourants (5.0 w/w).
- "REM 513.33" is a <u>comparable product</u> having the same composition of the invention product REM 513.32 but <u>without the</u> oleophylic smectite clay.

In particular, REM 513.33 has the following composition: a polyisoprene (10.0% w/w) obtained by the process comprising the steps of a) comminuting the solid polyisoprene Kraton IR 310 with molecular weight of about 3,000,000 b) depolymerising the comminuted solid polyisoprene of step a) to molecular weight of about 100,000; as hydrocarbon with 12-22 carbon atoms, isododecane (85.0% w/w); and colourants (5.0% (w/w).

- "REM 513.34" is a comparable product having the same composition of the invention product REM 513.32 but wherein the invention polyisoprene obtained by the process comprising the steps of a) comminuting the solid polyisoprene Kraton IR 310 with a molecular weight of about 3,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight of about 100,000, is substituted with a polyisoprene latex.

In particular, REM 513.34 has the following composition: polyisoprene latex IR401B (15.0% w/w), as oleophylic smectite clay, disteardimonium hectorite (6.0% w/w); as an aliphatic hydrocarbon with 12-22 carbon atoms, isododecane (73.5% w/w); and colourants (5.0% (w/w).

comparable product having the "REM 513.35" is a composition of the invention product REM 513.32 but wherein the invention polyisoprene obtained by the process comprising the steps of a) comminuting the solid polyisoprene Kraton IR 310 weight about 3,000,000 molecular of with a depolymerising the comminuted solid polyisoprene of step a) to a molecular weight of about 100,000 is substituted with a polyisoprene having very low molecular weight, i.e. with a molecular weight of about 400.

In particular, REM 513.35 has the following composition: a polyisoprene Syntesqual which is a hexaisoprene partially hydrogenated with molecular weight of 400 (10.0% w/w), as oleophylic smectite clay, disteardimonium hectorite (6.0% w/w); as an aliphatic hydrocarbon with 12-22 carbon atoms, isododecane (79.0% w/w); and colourants (5.0% (w/w).

The properties of the above tested composition have been summarized below.

## REM 513.32

Aspect: Creamy fluid stable product endowed with high long lasting film properties.

Drying time after application: 3 minutes

# REM 513.33

Aspect: Liquid unstable product, after 2 hours from its preparation the product shows an evident colour phase separation and thus making the product not applicable.

Drying time after forced application: 6 minutes

#### REM 513.34

Aspect: Doughy unstable product, visually unhomogeneous and thus making the product not applicable.

Drying time after forced application: 10 minutes

#### REM 513.35

Aspect: Semiliquid separated unstable product, after 24 hours from its preparation the product shows an evident superficial phase separation and thus making the product not applicable.

Drying time after application: 15 minutes

The film-forming property of the above products (i.e. REM 513.32, REM 513.33, REM 513.34 and REM 513.35) has been measured by means of the following transferability resistance test and saliva resistance test.

It is to be noted that, in order to carry out the above tests, the instable comparable products REM 513.33, REM 513.34 and REM 513.35 have been previously made homogeneous.

## Transferability Resistance Assay

The products have been applied on standard Leneta paper (Leneta 3NT-2 Translucent black & white) by means of a bar coated 10 microns applicator with the automatic applicator Elcometer at speed 11. After 5' drying, the sample was coupled with Leneta 3NT-2 paper, applied onto the automatic applicator and wiped with a 1Kg bar for 10 wipes. The transferability of the products from the applied paper to the coupled paper has been assessed.

After 10 wipes

REM 513.32 REM 51		REM 513.33	.3.33		REM 513.34		REM 513.35		
No	transfer	Very poor	transfer	Poor	transfer	Very	poor	transfer	

It is to be noted that the films of the comparable products REM 513.34 and REM 513.35 deposited on the paper were visually unhomogeneous.

As far as the comparable product REM 513.34 is concerned, it showed very evident colour streaks and its deposited film was easily removed by means of a finger wipe.

#### Salive Resistance Assay

The products have been applied on standard Leneta paper (Leneta 3NT-2 Translucent black & white) by means of a bar coated 10 microns applicator with automatic applicator Elcometer at speed 11. After 60' drying, the sample has been applied onto the automatic applicator and wiped with a uniformly wetted tampon of 1 g standard synthetic saliva fluid with a 1 Kg weight for five wipes in order to assess the product dissolution and its transferability onto the tampon.

After 5 wipes

REM 513.32	REM 513.33		REM 513.34		REM 513.35		
Clean	Slightly	colour	Slightly	colour	Colour	dirty	
tampon,	dirty	tampon,	dirty	tampon,	tampon,	slight	
no colour slight ring		3	slight rin	ıg	ring		
transfer							

5. From the above experimental data, it is evident that the combinative effect of the presence of the three components, i.e. 1) the polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) the oleophylic modified smectite clay and 3) an aliphatic hydrocarbon with 12-22 carbon atoms (REM 513.32) is essential in order to achieve a stable cosmetic composition

endowed with high film-forming property, which is easy to use and stable over a medium-long term and which provides for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes.

Indeed, as shown from the above data, only the invention product (REM 513.32) is endowed with a homogeneous creamy fluid aspect, has good film-forming property and a short drying time after application which makes it easy to use.

Furthermore, from the data shown above, it is also evident that the invention products (REM 513.32) is also a stable product.

On the contrary, all the comparative products (REM 513.33, REM 513.34 and REM 513.35) are unstable and with an unhomogeneous aspect and therefore unsuitable for the preparation of a cosmetic composition for application to facial skin, lips and eyelashes.

Moreover, from the above experimental data, it is also evident that not only the form of the polyisoprene, such as latex or solid, but also the selection of the molecular weight of the polyisoprene is critical in order to obtain the captioned cosmetic composition.

Indeed, the product wherein the polyisoprene has a low molecular weight (i.e. REM 513.35, MW 400) is unsuitable for the preparation of a stable homogeneous cosmetic composition.

6. The cosmetic composition of my invention is not suggested in the prior art documents.

Indeed, US 6 471 983 discloses a skin application agent containing a polyisoprene latex. In particular, in all the Examples of US 6 471 983, Kraton IR 401 is employed as polyisoprene latex.

The absence of a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, makes the product of US 6

471 983 unsuitable for the preparation of the cosmetic composition of the present invention which is stable, has high film-forming property and is endowed with a homogenous aspect.

At this purpose, I gave proof of the unsuitability of US 6 471 983 product with the experimental data of the analogous comparison product REM 513.34.

Moreover, US 6 471 983 does not teach the use of modified clay which on the contrary is described in a skin care composition of US 2003/0044469 but without the presence of any polyisoprene.

The absence of a modified clay, in particular of the oleophilic modified clay such as disteardimonium hectorire, leads to a unstable, unhomogeneous and thus not applicable product (see REM 513.33).

It is therefore clear that neither US 6 471 983 nor US 2003/0044469 suggest to select 1) a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) an oleophylic modified smectite clay and 3) an aliphatic hydrocarbon with 12-22 carbon atoms, as essential elements in order to achieve a stable cosmetic composition having high film-forming property and which provides for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

6/10/08 (date) (signature)

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